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## **12-month follow-up after brief interventions in primary care for family members affected by the substance misuse problem of a close relative**

**Short Title:** 12-month follow up of primary care interventions for family members affected by addiction

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## **12-month follow-up after brief interventions in primary care for family members affected by the substance misuse problem of a close relative**

**Short Title:** 12-month follow up of primary care interventions for family members affected by addiction

### **Abstract**

Following the publication of initial and 3-month data from a prospective cluster randomised comparative trial (Copello et al, 2009), an opportunistic 12-month follow-up was undertaken. The trial compared two brief interventions for use by primary health care professionals with family members (FMs) affected by the problematic substance use of a close relative. 90 out of 143 (63%) FMs in the trial were followed up at 12 months. Three validated self-completion questionnaires were re-administered: Symptom Rating Test, Coping Questionnaire, and Family Member Impact Scale.

At 12 months there were still no significant differences between FMs depending on which of the two brief interventions received. The initial improvements at 12-weeks on all of the measures (symptoms, coping and impact) were maintained, and further improved (FMs reported that their symptoms, their coping behaviours, and the impact on them of their relatives' substance misuse problem all continued to reduce). These improvements were unrelated to a range of demographic variables. FMs also reported a gradual improvement in their relatives' misusing behaviour over the three time periods.

In conclusion: following a brief intervention for affected FMs, either delivered in full via professional intervention or via a self-help manual following a brief introduction from a professional, both groups improve equally: there are significant and positive changes which are both maintained and further increased over a 12-month period, without any further formal delivery of the intervention.

**Key Words:** family members; alcohol and drug problems; randomised trial; 12-month follow-up; primary care; stress, coping and symptoms

## **Introduction**

A key issue in assessing the utility of therapeutic interventions is the sustainability of any post-intervention effects. This paper presents data from an opportunistic 12-month follow-up of participants within a prospective cluster randomised comparative trial, following the publication of initial and 3-month data (Copello et al, 2009).

The impact of alcohol and drug problems on family members is now well documented (Caetano, Nelson & Cunradi, 2001; Copello, Velleman & Templeton, 2005; Orford, Natera, Copello, et al 2005a; Orford, Natera, Davies, et al, 1998; Orford, Velleman, Copello et al, 2010; Ray, Mertens & Wiesner, 2007; Svenson, Forster, Woodhead & Platt, 1995; ).

A Stress-Strain-Coping-Support model (SSCS) model has been developed to describe the effects of such family problems (Orford, 1987, 1998; Orford et al, 2005a; Orford, Copello, Velleman and Templeton, 2010; Orford, Templeton, Velleman, et al, 2005b; Velleman & Templeton, 2003). The SSCS model states that the behaviour of the substance misuser causes stress for the family member, that stress leads to strain (for example, physical and psychological symptoms), and that the amount of strain any family member experiences from a given level of stress (caused as a result of living with a relative with a serious alcohol or drug problem) will be mediated by two key factors: how they cope with this problem, and the amount and quality of social support that they can access. Despite the high levels of stress and resulting strain present in these families, services on the whole remain focused on the misusers of alcohol or drugs, with little attention paid to these affected family members (Copello and Orford, 2002).

A brief intervention, based on the SSCS model and aimed at such family members, was developed for use in primary care (Copello, Orford, Velleman, et al, 2000a), and was tested for its feasibility (Copello, Templeton, Krishnan, et al, 2000b). The intervention consists of 5 steps (Copello et al, 2010), where the primary care professional listens (step 1), provides information (step 2), helps the family member look at the ways of coping they use and discusses alternatives (step 3), does the same with respect to support (step 4) and finally summarises the intervention, assesses whether further work is needed, and if so, refers on to an appropriate source. These 5 steps can all be undertaken within one session, but more usually they are undertaken over a number of sessions. In our experimental trials - feasibility studies in primary care (Copello et al, 2000b) and in specialist drug and alcohol services (Templeton, Zohhadi and Velleman,

2007), an randomised comparative trial (Copello, Templeton, Orford, et al, 2009, see below), and a feasibility study in Italy (Velleman, Arcidiacono, Procentese, et al, 2008) - we have limited the number of sessions to five.

Both the feasibility studies in England and the one in Italy used this professionally delivered intervention. Although all these studies used simple before-after comparisons, all showed significant improvements for family members on measures of symptoms and coping. Nevertheless, because these studies did not have a no-treatment control group, these improvements cannot be confidently attributed to the effects of the intervention. In the UK, a randomised comparative trial was conducted (Copello et al, 2009) which compared this brief (up to five session) intervention delivered by a primary care professional with an even briefer version, consisting of a single introductory session in which the professional introduced the intervention and then provided a self-help manual which assisted family members in working through the same steps on their own, in their own time. Family members in the professionally delivered version were also given a copy of the self-help manual. Copello et al (2009) have shown that family members in both groups showed significant improvements in physical and psychological symptoms of stress and in coping behaviour; and that no significant differences in outcome were found between the two groups.

The present paper examines the data from an opportunistic 12-month follow up of these family members. A key issue in assessing the utility of therapeutic interventions is the sustainability of any post-intervention effects. As such, follow-ups that look beyond the immediate post intervention period are of great importance. Such follow-ups enhance the results and clinical significance of any findings; and the lack of adequate longer-term follow-up is one of the most common criticisms levelled at potentially important findings where this has not been undertaken (Templeton, Velleman and Russell, 2010).

Twelve months after the start of an intervention has become a relatively standard follow-up period within a wide range of studies (eg Kelly, Halford & Young, 2000, who examined an intervention delivered to women with drinking problems and marital distress; Heather et al., 1987, who used a self-help manual based on behavioural principles to help problem drinkers) and that was the length used in the present study.

Such follow-up studies are undertaken for two reasons. First, they seek to examine the sustainability of any effects of an intervention: has the positive effect of the intervention remained over this 12-month

period, and if it has started to decline, by how much? Second, some interventions do not simply seek to sustain any effects: they seek also for effects to be augmented over time. These interventions are usually ones where changes are made to a person's behaviour or thinking as a result of the intervention, such that these more positive behaviours are then further enhanced over time. Studies which involve people utilising self-help manuals are often in this latter category, and as such these are particularly suitable for examination over a period which is greater than a relatively short 3-month post-commencement evaluation. This idea that, especially with self-help materials, change may continue and increase in the post-intervention period, has received some corroboration: for example, Spivak, Sanchez-Craig & Davila (1994) showed in a study which intervened with 140 problem drinkers that significant positive changes were noted at 12 months that were not seen at 3 months.

This paper will examine 5 questions:

- Was there differential drop-out – were the sample who were followed up at 12 months different in any important respects from those lost to 12-month follow-up?
- At the 3-month stage, there were no significant differences between the two interventions: did any emerge at the 12-month follow-up?
- Were the improvements in family functioning (ie symptoms and coping, and family members' ratings of changes to their situations) which were noted after 3 months, maintained, or even further improved, at 12-month follow up?
- Were there any differential effects related to, for example, sex, relationship between family member and misuser, or type of substance misuse?
- Did family members report any changes in their substance misusing relatives at the 12-month stage, or in the impact that their behaviour was having on them, and were any of these changes, if they occurred, attributed by family members to the 5-Step Intervention?

## **Method**

This paper reports a 12-month follow up of the 143 family members who received one of the two interventions described in Copello et al (2009). Copello et al (2009) reported on a cluster randomised comparative trial, of two levels of intensity of the 5-Step Intervention, delivered by primary health care professionals (PHCPs) in two study areas within the West Midlands and the South West regions of

England. That paper details the trial methodology, the study design, the flow of practices and family members, recruitment, randomisation, and so on. In summary, 197 PHCPs from 136 practices were randomised (by practice) to one of the two treatment arms, either a single introductory session alongside the provision of a self-help manual, or an intervention delivered throughout by a PHCP, also accompanied by the provision of a self-help manual. Practices across both areas included a mixture of those serving urban (including inner city and small town practices) and rural areas. The practices recruited included a typical range of practices representative of those within the UK health care system ranging from very large inner city practices with up to 12 General Practitioners to single-handed practices made up of a single family doctor. Following dropout before and after training, there were 78 'active' PHCPs aiming to deliver the full intervention and 90 the brief intervention. These PHCPs worked with 143 family members, 51 of whom received the full intervention and 92 the brief intervention. At 12 weeks, 129 (90%) family members were followed up; 45 (88%) in the full intervention, 84 (91%) in the brief intervention. There were no significant baseline differences between those family members lost to follow-up at 12 weeks and those who completed it.

The 12-month follow-up was an opportunistic addition to the original design, in that additional funds were obtained subsequent to the commencement of the study, specifically to allow for a postal 12-month follow-up.

## **Recruitment**

The recruitment of both professionals and family members into this trial has been described in Copello et al (2009). In brief, once PHCPs who were recruited into the study were randomised into and trained in delivering one or other of the interventions, each professional was then asked to recruit and then intervene with individual family members from amongst their own caseloads, with reference to the inclusion and exclusion criteria reported below. Most of these family members were attending for a normal primary care consultation, although a few were asked in by the PHCP because they already knew that the patient was living with a relative with a substance problem. Of the ones attending for a normal consultation, some were already known to the PHCP as being family members; with others it was only revealed when the PHCP asked them, by enquiring more deeply about their family circumstances. All family members of people with alcohol or drug problems were included if all the following applied: 1) the family member considered that the drinking or drug taking of a relative had been a major source of distress in the last six months; 2) the relative with the alcohol or drug problem had been drinking or consuming drugs

problematically at some point during the last six months; and 3) the relative with the alcohol or drug problem and the family member had been living under the same roof at some point in the last six months, or had face-to-face contact at least three times a week. Family members were excluded if they: 1) experienced alcohol or drug problems themselves and/or 2) had severe mental health problems.

The demographic characteristics of the 143 family members recruited into the study, divided between the two arms of the trial, are given in Copello et al (2009), Table 1. Eighty-five per cent of the family members were female, the family members' mean age was 45, 52% were partners of a substance misuser, 35% were parents to a substance misuser, 6% were adult children, and 6% were related in other ways (eg grandparent, aunt, etc.). Sixty per cent of the family members reported that their relative primarily misused alcohol, 40% drugs. Family members reported having lived with the misuse problem for a mean of 9 years.

For this 12-month follow-up, every family member (excluding those who specifically requested at either the initial or the 3-month meetings that they should not be followed-up at 12 months) was sent a standard letter about 10 days before the 'due date' (ie one that was 12-months from their commencement into the trial). They were asked to complete a questionnaire booklet containing the standardised questionnaires as well as a brief form outlining other useful information (relating to, for example, their use of services). A Freepost envelope was provided for return of the questionnaire booklet. The letter and questionnaire booklet was sent to the designated address listed on the consent form, or to a different designated address if one was given at the 12 week follow-up.

If the questionnaire booklet was not received within 1-2 weeks of the due date, the following procedures were followed, in order:

- The family member was telephoned at her or his main telephone number (as listed on the consent form) to check that the booklet had been received and to chase its return; if a message needed to be left instead of speaking directly to the family member, it was ensured that this was neutral with no mention being made about the topic of the research;
- The family member was written to again at the same address, and the booklet was re-sent along with a second freepost envelope;



- The family member's file was examined, and consideration was given to writing to the family member at a different given addresses (for example, work, another family member or a friend) or to chasing at other telephone numbers (for example, a mobile or work number);
- If no response had been received after these steps, the case was then discussed within the research team. In most cases, the PHCP who recruited the family member was then contacted and asked for information concerning the family member. If possible, a questionnaire booklet, letter & freepost envelope was then placed in a sealed envelope and left with the patient notes to be handed over when the family member next visited the practice;
- If the booklet was still not returned, further contact would be requested with the PHCP to see if the family member had attended the practice, and if so, if the sealed envelope had been handed over to the family member.

## **Outcomes**

Primary outcome measures included the Coping Questionnaire (CQ: Orford et al, 2005b) and the Symptom Rating Test (SRT: Kellner and Sheffield, 1973). These measure, respectively, ways of coping (such as engaged, tolerant-inactive and withdrawal coping that the family member uses to deal with the harmful impact of the substance problem), and common psychological and physical symptoms. A secondary outcome measure was also used: the Family Member Impact Questionnaire (FMI: Orford et al, 2005b), which measures the harmful impact of the substance problem on the family. Each of these three measures has been shown to be sensitive to change following our family member interventions (Copello et al, 2000b; Orford et al, 2005b). In each of these measures, lower scores are more positive, denoting fewer symptoms, fewer attempts at coping, and fewer negative incidents impacting on the family. Fewer attempts at coping is interpreted as a positive because we have found that the bulk of coping actions listed in the CQ are unhelpful in terms of family members' experience and health, in particular engaged and tolerant coping actions (Orford et al, 1998a; Orford et al, 2001). Previous research has shown therefore that family members' health is associated with less coping of most kinds (Orford et al, 2005b).

## **Sample size**

Because this was an opportunistic addition to the planned trial, power and sample size calculations were not undertaken initially on numbers aimed for at 12 months. The original trial calculation aimed to recruit a minimum of 60 family members per intervention (120 in all), and to follow up 90% of them after 12 weeks. An effect size of 0.5 was deemed necessary in order for the difference to be clinically significant.

With a 1-sided alpha of .05, an *N* of 50 in each group is necessary to achieve a power of .80 (Cohen, 1992). Once the additional funding became available, we then aimed to obtain 12-month data from 70% of the original sample. The actual sample size achieved in the main trial is reported above and in Copello et al (2009). 12-month data were obtained from 90 (63%) family members at 12 months, 32 (63%) from the full intervention arm, 58 (63%) from the brief intervention.

## **Ethical approval**

The study was approved by the Multi Centre Research Ethics Committee and local ratification was obtained from all relevant Local Research Ethics Committees.

## **Analyses**

1. The baseline data from those who were followed up at 12-months was compared with baseline data from those who were not followed up at 12-months, to clarify the extent to which the groups differed due to attrition.
2. Using the entire sample available for each time period, data from those receiving the Full intervention were compared with those receiving the Brief intervention.
3. For those for whom we had 12-month data, levels of family functioning (ie symptoms and coping, and family members' ratings) were examined, to see if the improvements noted after 3 months had been maintained, or even further improved, at 12 month follow up.
4. A number of other related areas also were examined, including whether differential effects were found, depending on the sex of either the family member or the substance misuser, the type of relationship that the family member had with the problem user (for example parent versus partner versus other) and the type of substance the relative misused (alcohol versus illegal drugs).
5. Changes over time in family members' views on the extent to which their misusing relatives had changed their misuse, and the impact that any misuse had had on them, were examined for those for whom we had 12-month data. Were changes, if any occurred, attributed to the 5-Step Intervention by the family member?

Statistical analyses were conducted using SPSS for Windows, release 14. The data were analysed twice, first using the dataset comprising the sub-sample of respondents at 12 months who provided complete data, and then on a second dataset in which missing data were imputed at baseline, and at 12-week and 12-month follow ups for questionnaire measures, provided that no more than 25% of the data were

missing. Not surprisingly, given the pragmatic nature of the study in primary care and the method used for collection of baseline data through the professionals delivering the intervention, we found that baseline data had more missing values than the follow-up data that were collected by the project researchers (12-week), or by postal questionnaire (12-month). The results from the two datasets were very similar so only those from the imputed dataset are presented in this paper.

## Results

### 1. Were those followed up at 12-months different from those not followed up?

The 90 (63%) family members from whom 12-month data were obtained were compared on all relevant demographic details with those who were not followed up at 12-months. There were no significant differences between these subsamples on any of the following baseline measures: sex of family member or of substance misusing relative; the relationship between family member and misuser; whether the misuser's problem related to alcohol, drugs, or both; the age of the family member or the misuser; how long the family member considered the misuser had had a problem; whether the relative lived with the family member; whether the family members was in employment; the family member's ethnicity.

Similarly, there were no significant differences at baseline between these two subsamples on any of the three questionnaire measures: the two primary outcome measures of Coping and Symptoms, and the measure of Impact or stress that the relative's misuse caused the family member.

87 out of the 90 family members for whom we obtained 12-month data also gave 12-week data. 3 of these 90 family members had baseline data but did not provide a 12-week interview.

### 2. Were there still no differences at 12-months between those receiving the Full intervention and those receiving the Brief intervention?

At 12 weeks the primary analysis found no statistically significant differences between the two trial arms on the two main outcome measures, namely symptoms and coping (Copello et al, 2009). Table 1 shows that there were still no significant differences at 12 months. Table 1 also shows that there were no significant differences between the two conditions on the secondary measure of the impact of the substance misuse on the family member, over the three time periods (baseline, 3-months, 12-months).

TABLE 1 ABOUT HERE

### 3. Have the improved levels of family functioning (ie symptoms and coping, and family members' ratings) noted after 3 months been maintained, or even further improved, at 12 month follow up?

#### *Questionnaire results*

Table 2 shows that there was a significant reduction in Total Coping, from baseline to 12 weeks ( $t(166) = 6.11, p < 0.0005$ ) and from 12 weeks to 12 months ( $t(79) = 2.62, p = 0.011$ ). Table 2 also shows a significant

reduction in Total Symptoms, from baseline to 12 weeks ( $t(113) = 4.02, p < 0.0005$ ) and from 12 weeks to 12 months ( $t(81) = 2.69, p = 0.009$ ). The results relating to Impact are discussed in sections 4 and 5, below.

TABLE 2 ABOUT HERE

#### *Other Data related to Family Functioning*

Family members were also asked to rate any changes to their situation, at both 12 weeks and 12 months.

At 12 weeks, 77/126 (61%) stated that things were either much or a bit better; 30 (24%) saw no difference, and 19 (15%) thought that things were much or a bit worse. The 77 people who considered that there had been positive changes were asked to say how much of the change they considered was attributable to the 5-Step Intervention. 16 (21%) thought that none of the change was related to the intervention; 53 (69%) thought that some of the change was due to the intervention (2 (3%) ‘completely’, 20 (26%) ‘quite a lot’, 21 (27%) ‘moderately’, 10 (13%) ‘only a little’). Data related to this question was missing from 8 respondents.

At 12 months, 50/89 (56%) thought things were much or a bit better; 21 (24%) saw no difference, and 18 (20%) thought that things were much or a bit worse. Again, the 50 people who considered that there had been positive changes were asked to say how much of the change was attributable to the 5-Step Intervention. 17 (34%) thought that none of the change was related to the intervention; 32 (64%) thought that some of the change was due to the intervention (1 (2%) ‘completely’, 7 (14%) ‘quite a lot’, 10 (20%) ‘moderately’, 14 (28%) ‘only a little’). Data related to this question was missing from 1 respondent.

Although this was a postal questionnaire study, family members were asked to “*Please write anything else that you have to say about how your situation has been...*”. Some of the key qualitative comments from family members relating to their perceived positive changes are shown in Table 3.

TABLE 3 ABOUT HERE

It is also the case that the intervention seemed to be as powerful with family members who had suffered with their relatives’ problems for a long time as it was with those whose problems were only relatively recent. In those followed-up for this 12-month assessment, the mean number of weeks that family

members had been living with their relatives' substance misuse problems was even longer than at baseline (due to the fact that these data were recorded 12 months after the baseline data): at 12-month follow-up, family members had lived with the problem for an average of 9.5 years (497 weeks, *sd* 401), with the maximum number of years/weeks being 35 years (1820 weeks). There was no differential drop-out: those with longer-standing or perceived more intractable problems did not leave the trial at a faster rate. And there was no significant relationship between the length of time that the family members reported having lived with the problem and whether or not they considered that there had been positive changes in their life over the previous 12 months ( $r=-0.18$ ,  $p=0.114$ ).

#### **4. Were differential effects found relating to various demographic variables?**

Improvements in how the family member coped, and their symptoms, and in rated impact, all reduced from baseline to 12 weeks and on to 12 months, for family members irrespective of their sex, and irrespective of the sex of their using relative. There were some minor differences but none were statistically significant.

Figure 1, using data from the General Linear Modelling component of SPSS, shows that there are no major differences in either the impact of the substance problems reported by the family members nor the amount of coping they use, and that all of these improve significantly over the three time periods. On the other hand, the data do show that there are differential amounts of symptoms, with the 28 (at 12-months follow-up) family members whose relative had a drug problem demonstrating greater symptom levels than did the 45 whose relative had an alcohol problem, and with the 6 family members whose relative had both alcohol and drug problems showing the lowest levels of symptoms. These differences in symptom levels across the three substance conditions are significant (GLM, test of between subject effects,  $F=4.29$ ,  $p=0.017$ ).

FIGURE 1 ABOUT HERE

The finding of a continuing reduction in impact, coping and symptoms over the three time periods is also found in relation to the type of relationship between family member and misuser. One element is different, however. Parents of substance misusers report higher levels of symptoms than do family members who are partners or (adult) children of misusers, and their symptoms levels, whilst still reducing over the three time periods, reduce at a far slower rate and do not reach the lower levels that the other two

types of family member attain. These are significant differences (GLM, test of between subject effects,  $F=3.81$ ,  $p=0.027$ ).

**5. Did family members' views on the extent to which their misusing relative had changed their misuse, and the impact that any misuse had had on them, change over time? Were changes, if any occurred, attributed by the family member to the 5-Step Intervention?**

Family members were asked about whether their substance misusing relative still had an active problem at each of the three data gathering points, baseline, 12-weeks and 12-months. Looking only at those family members for whom we have follow-up information, these data show a gradual improvement, with significantly *fewer* people considering that their relative did have a problem, and significantly *more* family members considering that their relative did not have a problem, over the 3 months between baseline and the first follow-up, and again with these numbers continuing to change significantly over the subsequent 9 months. So at baseline, 74/85 (87%) stated that their relative definitely or probably *did* have an active problem, at 12 weeks that number had reduced to 60/86 (70%), and at 12 months it had reduced to 55/90 (61%). Conversely, the numbers who considered that their relative definitely or probably *did not* have an active problem changed from 4/85 (5%) at baseline, 16/86 (19%) at 12 weeks, and 21/90 (24%) at 12 months. The numbers who were unsure were 7 (8%) at baseline, 10 (12%) at 12 weeks, 13 (15%) at 12 months. These changes were statistically significant: from baseline to 12 weeks ( $Chi Sq = 16.75$ ,  $p=0.002$ ), and from 12 weeks to 12 months ( $Chi Sq = 12.23$ ,  $p=0.016$ ).

This was also corroborated by the scores on the Impact Questionnaire: ie family members' perceptions of the stress that their substance misusing relative was causing them. Table 2 shows that there was a significant reduction in the Impact of their relatives' behaviour on family members, from baseline to 12 weeks ( $t(108) = 4.70$ ,  $p<0.0005$ ) and from 12 weeks to 12 months ( $t(83) = 3.27$ ,  $p=0.002$ ). Table 1 compares the Impact Questionnaire scores across the two conditions of Brief and Full interventions and shows that there were no significant differences between the family members within the two conditions at any of the three time periods: scores on Impact for both groups fell significantly over time.

Family members were also asked at baseline and 3-months whether their relative's problem had changed in the previous three months, and at the 12-month follow up whether the problem had changed over the previous 12 months. There was a significant increase in the percentage of family members who considered that their relative's problem had improved over the previous 3 months at the first follow up

(from 20% to 49%,  $\chi^2 = 12.35$ ,  $p=0.015$ ), and over the previous 12 months at the 1-year follow up (from 20% to 53%,  $\chi^2 = 15.53$ ,  $p=0.004$ ), compared to how these family members rated the problem over the three months prior to joining the trial.

Family members were also asked to what they attributed these improvements, if there were any. At 12 months, 10 (23%) out of the 43 family members who thought that their relative's substance problem had improved over the preceding 12 months thought that this was due to their (the family member's) involvement in the project.

#### *Do family members' symptoms and coping improve, even if their relative does not?*

As stated above, at 12 months, 53% considered that there had been positive changes in their relative's misuse, with 47% considering that the misuse was unchanged or even worse. A key question is whether or not, using only those family members whose relatives were unchanged or worse, there were still positive changes in coping and in symptoms. Using only data from the 37 family members who considered that their relative had not changed (30) or become worse (7), and comparing scores for this group between baseline and the 12 month follow up, there were still significant improvements in Total Coping ( $t(33) = 3.03$ ,  $p<0.005$ ) and Total Symptom levels ( $t(33) = 2.12$ ,  $p=0.041$ ) albeit smaller improvements than those achieved using the entire sample. Interestingly, perceived Impact of the substance misuse in this sub-group of family members who considered that their relative's misuse had not changed or become even worse also reduced over time, although for them this reduction only occurred over the first 12-weeks ( $t(33) = 2.53$ ,  $p=0.017$ ) and was not significant by the time of the baseline to 12 month comparison ( $t(33) = 1.58$ ,  $p=0.123$ , ns).

## **Discussion**

Five areas have been examined in this paper, and important results were found in each.

First, although the 12-month follow-up group comprised only 90 of the original 143 family members (63%), comparisons with those not followed up at 12 months showed that there were no significant differences on any measure. This follow-up group is representative of the wider group who were initially recruited, and there has been no differential drop-out.



Second, in terms of the differences between the two conditions, the full professional-delivered intervention accompanied by a self-help manual, versus a single introductory session also with the self-help manual, at 12-months there were still no significant differences between family members on any of the measures of impact, coping and symptoms.

Third, in terms of family member functioning, the significant reductions in family members' coping responses over the first three months, showed further reductions over the subsequent nine months. In the same way, the improvements which had been noted at the 12-week stage in the levels of symptoms that family members experienced - probably as a result of both the stressful impact of their relatives' alcohol or drug problems and the resulting levels of coping behaviours that they needed to exhibit - reduced further over the subsequent nine months.

The majority of family members also rated their situation as changed for the better after the intervention had finished, and for a substantial time after that, and again the majority thought that the changes in their situation were due at least in part to the intervention that they had received.

Fourth, these improvements over the three time periods were also examined in relation to a number of other variables. In general, the improvements over time were unrelated to any of the variables which were examined. There were however two exceptions to this. One concerned the type of substance the family member's relative used, where drug problems were associated with higher levels of symptoms in the family members than were alcohol problems. This has not been observed in other studies on family members of substance misusers undertaken by this research team using these measures, and conducted in different countries (UK, Mexico, Italy), where no significant differences in symptom levels have been found in relation to alcohol versus drugs (eg Orford et al, 1998a; Arcidiacono et al, 2010), nor across a wide range of licit and illicit drugs (Velleman et al, 1993), nor indeed other related behaviours such as gambling (Orford et al, 2005b).

The second, and more important, exception is the finding that parents had higher symptom levels than did partners, and that, although these parents' symptom levels did improve over the three time periods, they did so at a slower rate than did the symptoms of partners. Indeed, at 12 months the parents' symptom levels had only reduced to the levels that the partners started with. These data also show that, although parents had higher levels of symptoms, there were no differences between parents and partners in terms of

the reported levels of problematic behaviour that their relatives exhibited (the FMI scores) or the number of coping behaviours which they used. This could suggest that the strain (in terms of symptom levels) caused by any given level of stress (the impact) is greater on parents than it is on partners.

Although some research has been undertaken on the differential effects of a relative's substance misuse between parents and partners (Velleman et al, 1993; Orford et al, 1998b, 2001; Arcidiacono et al, 2010) other research has tended to look solely at parents or parents and siblings (eg Butler and Bauld, 2005, Barnard, 2005; Oreo and Ozgul, 2007). Velleman et al (1993) in their study of family members of illicit drug users, also found few differences between parents and partners in relation to the overall frequency of problematic behaviours with which they were confronted (what is termed 'impact' in this present study). They did find that there were marked differences in the patterns of events which they experienced (with partners reporting more physical violence, unpredictable mood changes, threatening behaviour, pressure for money, and damage to property and parents reporting more lying, manipulation, and self-neglect on behalf of their drug-using child) but only one of all of these differences was statistically significant. Unfortunately, Velleman et al (1993) did not report on whether or not there were differential overall rates of symptoms between parents and partners. Orford et al (1998b) reported a qualitative examination of the stresses and resulting strain experienced by 24 family members, 12 from an English sample and 12 from a Mexican sample. No major differences were seen between parents and partners in either stresses experienced or signs of strain reported. Orford et al (2001) reported both quantitative and qualitative results from the larger cross-national study from which the sub-samples analysed in Orford 1998b had been drawn. They found different patterns of coping between parents and partners, but again differential symptom levels between parents and partners were not specifically examined. Arcidiacono et al (2010) examined all four aspects of stress, strain, coping and support within samples drawn from three different regions of Italy. They did examine whether there were differential levels of symptoms between parents and partners, and found in their study that there were not. The differential (and more severe) level of strain on parents (ie their higher level of symptoms) found in this present study is an area which needs closer attention.

Finally, family members also reported a gradual improvement in their relatives in terms of their misusing behaviour over the three time periods. There was a significant increase in the percentage of family members who considered that their relatives' problems had improved over the previous 3 months at the first follow up, and over the previous 12 months at the 1-year follow up, compared to how these family

members rated the problem over the three months prior to joining the trial. Around one quarter of the family members who thought that their relatives' substance problems had improved over the preceding 12 months attributed this at least in part to their (the family members') involvement in the project. There was similarly a significant reduction in the reported impact of their relatives' substance misuse on the family members over the time periods, with again a significant further decrement in impact at 12 months. There were significant improvements in symptoms, coping, and impact even for those family members who considered that their misusing relative had *not* improved or had got even worse.

There are three major implications to these results presented above.

The first implication emerges from the fact that at 12-months there is still no significant difference between the results for the briefer form of the intervention as opposed to the longer form: in both groups there is immediate improvement after the end of the intervention, and then further continued improvement over the subsequent 9 months. One conclusion from this may well be that it is much more cost effective to provide the brief form. For this reason, the research group have now developed an on-line version of the intervention so that family members can access the 5-Step Intervention directly (<http://www.alcoholdrugsandfamilies.nhs.uk/>). This on-line version is currently being evaluated (Ibanga, 2010). On the other hand, it remains the case that many family members and many professionals stated that they preferred the longer, professional-delivered intervention (Orford et al, 2007 a, b). It may be that two of the main UK health service agendas at present, patient choice versus cost effectiveness, are in conflict over how best to implement this intervention.

The second implication of these 12-month follow-up results is that they provide a number of pieces of extra evidence for the usefulness of the 5-Step Intervention. They suggest that a relatively simple and brief intervention (and even the full intervention is a brief one, lasting up to 5 session) enables family members to re-appraise their lives with respect to their substance misusing relative, to see the impact as being less of a strain, to revise their methods of coping, and to have a resulting reduction in the level of symptoms they experience. So far, all studies which have tested this intervention have found similar results, in both the UK and Italy, the two countries where this intervention has been tested so far. Although most of these studies have used a before-after design, and the single randomised comparative trial used a comparison of two versions of the intervention, we have also shown and argued elsewhere (eg Orford et al 2007 a, b) on the basis of the results of interviews with both family members and

professionals that we have confidence that it is the intervention which is leading to positive change for family members. Hence these 12-month findings strongly corroborate the findings from the initial 3-month follow up (Copello et al, 2009); and also corroborate the findings from previous studies in the UK (Copello et al, 2000b; Templeton et al, 2007) and in Italy (Velleman et al, 2008).

Another piece of evidence for the usefulness of the 5-Step intervention is the result suggesting that the intervention seemed to be as powerful with family members who had suffered with their relatives' problems for a long time as it was with those whose problems were only relatively recent. This is an important finding. Because many family members suffer from a relative's problematic substance use for many years (at 12-month follow-up, family members had lived with the problem for an average of 9.5 years, with the maximum length being 35 years), it might be thought that a relatively brief and quite simple intervention would be less likely to help them. Family members who have lived with this stressful experience for many years might feel that they already had tried many of the ideas within the 5-Step intervention, and might feel that it was all 'too little, too late'. The fact that the evidence is suggesting that this is not the case, and that symptoms and coping levels improve just as much for people who have lived with these problems for many years, is further evidence for the usefulness of this intervention.

A further piece of evidence for the usefulness of the 5-Step intervention is the fact that, even when family members considered that their misusing relative either had not improved or had got even worse, these family members still showed significant reductions in symptoms and coping behaviours.

A final piece of evidence suggesting that the 5-Step intervention is useful is the suggestion that the intervention with the family member was associated with reported positive changes in the substance misuser. Of course, an association cannot imply a causal link, and indeed, it may be that the changes in coping and symptoms of the family members (and in perceived Impact) may have occurred because the substance misuse may have improved. We would argue that this interpretation is less likely due to the very great lengths of time that these family members have been suffering with this problem (an average of 9.5 years, rising to a maximum of 35 years, as outlined above). It seems unlikely that, after so many years of living with these problems, so many misusing relatives would have all positively changed their substance misuse just at the time that their family member also was finally offered some help. It is also the case, as reported above, that the majority of family members rated their situation as changed for the better both after the intervention had finished and at the 12 month follow up, and that the majority thought

that these positive changes in their situation were due at least in part to the intervention that they had received. Nevertheless, it is also possible that some family members were recruited into this study linked to their substance misusing relative also entering treatment or deciding that they wished to start to change their misusing behaviour.

The final implication of the results presented in this paper relates to the fact that the improvements on all measures continued well past the end of the intervention itself, and indeed there was continued improvement over the 9-month period following the first follow-up. The significant reductions in the level of their relative's problematic behaviour as rated by the family members (the FMI scores) which was reported over the first three months, reduced significantly again over the subsequent nine months. In the same way, the significant reductions in family members' coping responses over the first three months further reduced significantly over the subsequent nine months; and the family members' reduced levels of physical and psychological symptoms at the three month stage were also further reduced over the subsequent nine months.

The nature of the study design means that we cannot conclude that there is a causal relationship between the intervention and these sustained and in some cases increased improvements over time. The fact that such improvements were seen in both groups within this randomised comparative trial and that there was no substantial difference between groups, suggests that one possibility is that the natural history of these problems in affected family members is towards improvement.

Although possible, we think that this is unlikely. Because family members at baseline had been living with their relatives' substance misuse problems for an average of nearly 9 years (459 weeks, *sd* 384), with some having lived with the problems for almost 35 years (1812 weeks), it is unlikely that the natural history of these problems would mean that so many of them would improve at just the time that they received an intervention, if their improvement was not related to that intervention. An alternative interpretation therefore is that these improvements are related to the intervention.

Another possible explanation might be that either family members or misusing relatives were accessing additional support over this 12-month period, and hence the positive changes reported here might be attributable to the results of other interventions or professional support services. However, from the 12-month questionnaire we know that only 3% of those followed up at 12 months had accessed any help

from the practice counsellor at their surgery<sup>1</sup>, only 9% had sought (never mind received) any help from a substance misuse agency, and only 3% had sought help from any other type of helping agency or professional. The data relating to any interaction between changes in their misusing relative's drinking or drug-using status and positive changes in family members has already been discussed above. It is highly unlikely therefore that accessing other interventions or additional professional support is the reason for these positive changes.

The 5-Step Intervention is based on the SSCS model, itself underpinned by empowerment ideas (Orford 2008). Family members have been largely neglected by services (Copello and Orford, 2002) and have had to cope as best as they can, usually on their own, with the stress and resulting strain that living with someone with a serious substance misuse problem causes.

The 5-Step Intervention explicitly seeks to empower these family members to re-appraise both the impact that their relatives' behaviours have on them, and the ways they respond to and cope with these behaviours. This is done by suggesting various re-appraisal skills that family members can learn to use, and the results from this 12-month follow-up suggest that many family members do learn them, setting in motion a set of different appraisals and responses which continue long after the end of the intervention as such. It is also possible that the provision of the self-help manual, which the family members keep, may enable them to return and remind themselves about key aspects of the intervention over this period. It is unlikely that this is the main explanation, however: only 25% (22/87) of those followed-up at 12 months stated that they had re-used the self-help manual over the previous 9 months.

A clear implication of these findings is that, even if interventions are initially delivered by a professional (and even in the brief form of this intervention, there was a single professional-led session), if skills for change are transferred and people feel empowered to make those changes, then they do not need to be reinforced by continued professional involvement (although it is of course possible that family members in one or both groups would have improved to an even greater degree if there *had* been continued professional involvement). As reported above, there was no relationship between length of time that family members had lived with the problem and how helpful they found the intervention to have been. This findings links with findings from other work where brief and/or cognitive-behavioural interventions are delivered which have a continued impact due to this transfer of both skills, and people's

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<sup>1</sup> In the UK, a 'surgery' is a room or office where a doctor or other PHCP sees and treats patients.

empowerment to use them (Bailer et al, 2004; Durham et al, 2003; Eack, 2010; Kelly et al, 2000; Spivak et al, 1994; Wallerstein, 2006).

Finally however, it is important not to overstate the usefulness of this 5-Step intervention. Although the mean reductions in coping and symptoms across both groups of family members were statistically significant, it could be questioned whether these were clinically significant changes. Copello et al (2009, p56) addressed this, stating that *“We believe that in many cases the changes were clinically significant. Evidence in support of that statement comes from analysis of the forms completed by professionals after each consultation, semi-structured interviews held with family members 12 weeks after recruitment, telephone conversations with professionals at the same time and semi-structured interviews held with each professional at the end of the project. Although not all benefited, a number of family members described transformations in their ways of coping with the problem, whether they received the full or brief form of the intervention. It was common to hear family members describe some combination of the following: an increased awareness of the nature and extent of the relative’s drinking or drug use and its effects in the family; a greater acknowledgement of the family member’s own needs and rights; a strengthening of the family member’s resolve to be assertive about plans and expectations; and a general calming and reduction in stress symptoms. Professionals often described consistent changes for their family member patients. The latter were often described as being happier, more confident, more assertive, less anxious or depressed and/or eating better or smoking less. They had also noticed a shift of focus on the part of the family member away from a dominating and emotionally draining concern with the problem drinking or drug-taking relative, and an increase in personal confidence.”*

Nevertheless, the mean levels of improvement on the two primary measures, whilst statistically significant, do not mean that people, after the intervention, were scoring within the ‘normal’ range.

The Symptom Rating Test has been widely used over the past 30 years, and Cochrane & Stopes-Roe (1980) obtained general population norms within the UK from a community control group in England and Ireland (mean total SRT = 8.0), which they compared to a group of English psychiatric outpatients and day-patients (mean total SRT = 24.6). The family members in the study reported in this present paper scored 32.7 at baseline, falling to 28.4 at 3-months and to 25.3 at 12-months. The family members reported on in a feasibility study undertaken in Italy (Velleman et al, 2008) started with mean SRT levels of 32.9 which fell to 28.9, 3 months after the 5-Step Intervention. This implies that the family members

recruited to these studies had, at the start, symptom levels which were considerably higher than a sample of psychiatric in- and day-patients, and that following the intervention their symptom levels only dropped to those experienced by that sample of psychiatric patients.

There are no general population norms for the Coping Questionnaire, but this too has been used by many research groups across the world since it was first developed more than 30 years ago (Orford et al, 2005b). The nearest to a general population norm comes from a major longitudinal study of untreated heavy drinkers who did not see their drinking as problematic at the time of entry to the study (Orford and Dalton, 2005). Family members of these drinkers completed the CQ at that time, and their mean scores are significantly lower than those from family members entering studies where the 5-Step Intervention has been used (Engaged: 8.4; Tolerant-inactive: 4.6; Withdrawal: 8.2). In this present study, family members' CQ scores fell, but not to the levels which this 'non-problem' sample showed. Engaged coping fell from 27.1 at baseline to 22.9 at 3-months and 20.1 at 12-months; Tolerant-inactive coping fell from 14.63 at baseline to 12.3 at 3-months and 10.2 at 12-months; Withdrawal coping fell from 6.9 at baseline to 5.9 at 3-months and 5.7 at 12-months. Similarly, in the Italian study (Velleman et al, 2008) the three types of coping changed from 30.5 (Engaged) 14.2 (Tolerant-inactive) 7.4 (Withdrawal) at baseline to 28.1, 11.2, and 8.1 at 3-months.

These data show that the 5-Step Intervention is associated with statistically significant changes on these primary measures, but they also show that these family members, following the intervention, still remain with symptom levels and levels of coping behaviours which are far higher than those which problem-free individuals show. It remains a challenge to develop this or other interventions so that affected family members can reduce their symptom and coping levels even further.



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## Clinical trial registration

Trial number: ISRCTN46411517 Current Controlled Trials (CCT).

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**Table 1: Full versus Brief Intervention: Coping, Symptoms and Impact, (Means, SD, N)<sup>12</sup>**

		Baseline	12-weeks	12-months
<b>Coping</b>	Full	52.28 (16.3) N=49	43.89 (20.1) N=44	41.98 (19.8) N=29
	Brief	52.15 (13.8) N=88	45.15 (18.7) N=78	39.01 (18.6) N=55
<b>Symptoms</b>	Full	33.34 (12.9) N=47	29.96 (14.6) N=44	22.74 (15.7) N=31
	Brief	33.93 (11.8) N=89	29.69 (12.9) N=77	26.71 (14.0) N=55
<b>Impact</b>	Full	30.57 (8.7) N=47	28.27 (10.1) N=43	22.31 (13.1) N=32
	Brief	30.66 (7.7) N=87	26.48 (10.6) N=74	23.47 (12.3) N=58

<sup>1</sup> All available data is used at each time period, Total N's: Baseline = 143, 12-week = 129, 12-month = 90; lower scores denote improvements

<sup>2</sup> None of the differences on any pair of scores (Full vs Brief), at any of the time periods, is significant. 'r' ranges from -0.49 to 1.21.

**Table 2: Coping, Symptoms and Impact (Means, SD, N) over the three time periods, aggregated over the two interventions <sup>1</sup>**

		Baseline	12-weeks	12-months
<b>Coping</b>		<b>51.78</b> (14.5) N=88	<b>44.06</b> <sup>2</sup> (18.2) N=87	<b>40.04</b> <sup>3</sup> (19.0) N=84
<b>Symptoms</b>		<b>32.74</b> (12.0) N=88	<b>28.42</b> <sup>4</sup> (13.8) N=86	<b>25.28</b> <sup>5</sup> (14.6) N=86
<b>Impact</b>		<b>30.68</b> (7.9) N=86	<b>26.68</b> <sup>6</sup> (10.1) N=85	<b>23.06</b> <sup>7</sup> (12.5) N=90

<sup>1</sup> Using data solely from those F/U at 12 month; lower scores denote improvements

<sup>2</sup> significant reduction in Coping from baseline to 12 weeks ( $t(116)=6.11, p<0.0005$ )

<sup>3</sup> significant reduction in Coping from 12 weeks to 12 months ( $t(79)=2.62, p=0.011$ )

<sup>4</sup> significant reduction in Symptoms from baseline to 12 weeks ( $t(113)=4.08, p<0.0005$ )

<sup>5</sup> significant reduction in Symptoms from 12 weeks to 12 months ( $t(81)=2.69, p=0.009$ )

<sup>6</sup> significant reduction in Impact from baseline to 12 weeks ( $t(108)=4.70, p<0.0005$ )

<sup>7</sup> significant reduction in Impact from 12 weeks to 12 months ( $t(83)=3.27, p=0.002$ )

**Table 3: Qualitative comments from family members relating to their perceived positive changes**

“(Although my relative has not changed much), I have improved due to my involvement” (family member’s emphasis);

“Had the confidence to be more open about the problem and to challenge the user’s actions while supporting him”;

“I am no longer with my partner, we’ve been split up for 6 months, my life has improved 100%: in my opinion the best way to deal with these problems is to leave the partner with problem;”

“I have learned: detachment/ my wife can not be ‘controlled’/ she must decide when to stop/ all I can do is to try to limit damage;”

“I’m more relaxed and less arguing has occurred”;

“I think I’m stronger, I don’t blame myself, I don’t let his drinking affect me as much as it did”;

“My partner realised how unhappy I was, he started controlling his drinking habits. And I am now no longer on anti-depressants. Thank you for your help”;

“Sorry for the delay in returning this form – I have moved to XXXXXX (Tel. XXXX). Life is good – myself and my son are happy. I am doing well, still getting on with my life. [My misusing relative] is not changing and also doing his own thing”;

“We split up, my health has improved. I still feel partly responsible for his problem, because that’s what he tells me”.

Figure 1: Type of substance being misused (N= 43-45 relatives misuse alcohol, 27-31 misuse drugs, 5-6 misuse both alcohol and drugs; ‘R’ is the substance misusing relative). Impact, coping and symptoms for family members, across three time periods: (1) baseline, (2) 3-months and (3) 12-months.

